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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,977	04/16/2004	Eugene H. Gans	01-40326-US-C	8741

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	PAPER NUMBER
1617	
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02/26/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/825,977	GANS ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-10 and 13-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-10 and 13-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/10/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of applicants' remarks, 132 declaration, and terminal disclaimer submitted November 16, 2007 is acknowledged.

Double Patenting Rejections

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1, 2, 4-10 and 13-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,765,001. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims herein are generic to the claims in '001.

Claim Rejections 35 U.S.C. 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4-7, 10 and 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poulson (US 3,94234,013).

Poulson teaches a topical pharmaceutical composition comprising a propylene glycol and two or more corticosteroids (0.001-0.5%), e.g., fluocinolone acetonide, citric acid (0.01 g or 0.01%), Tween 60 (2 g or 2%), Span 60 (2.0 g or 2%), stearyl alcohol (15 g or 15%), and mineral oil (3.0 g or 3%), see in particular Example 2, col. 17, claim 1-15, and 27, compound B in particular. Poulsen further teaches that the preferred weight percentage of water/glycol mixture of the base is between 70 and 95%, in cream composition see col. 11, lines 44-60, see also col. 10, CREAM BASE, and 94.8-99% in lotion. Poulson also teaches the amount of surfactant is in the composition is about 0.1 to 5 %, and preferred range is 0.5 to 2% in lotion (col. 14, line 30-56). Fatty alcohol is in the range of 1-20%, preferred 5-10% in cream (col. 10, line35-42) and the amount of fatty ester in lotion is about 0.10 to 10%, preferred 0.5-2% (col. 14, lines 50-55). Poulsen (USPN 3,934,013) does not teach some of the particular percentages of corticosteroid or propylene glycol herein.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ corticosteroid, and propylene glycol and fatty ester (or fatty alcohol) in the particular weight percentages claimed herein. Note the fatty alcohol or ester is considered as to meet the limitation of penetration enhancer herein since it is well known that fatty compound would enhance the penetration of topical therapeutical compounds See, e.g., page 2, the third paragraph in the specification.

One of ordinary skill in the art would have been motivated to employ corticosteroid and propylene glycol in the particular weight percentages claimed herein because ranges covering the instant weight percentages are taught to be useful in topical formulations by the prior art.

4. Claims 1, 2, 4-7, 10 and 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poulson (US 3,94234,013), in view of Bennett (IDS).

Poulson teaches a topical pharmaceutical composition comprising a propylene glycol and two or more corticosteroids (0.001-0.5%), e.g., fluocinolone acetonide, citric acid (0.01 g or 0.01%), Tween 60 (2 g or 2%), Span 60 (2.0 g or 2%), stearyl alcohol (15 g or 15%), and mineral oil (3.0 g or 3%), see in particular Example 2, col. 17, claim 1-15, and 27, compound B in particular. Poulsen further teaches that the preferred weight percentage of water/glycol mixture of the base is between 70 and 95%, in cream composition see col. 11, lines 44-60, see also col. 10, CREAM BASE, and 94.8-99% in lotion. Poulson also teaches the amount of surfactant is in the composition is about 0.1 to 5 %, and preferred range is 0.5 to 2% in lotion (col. 14, line 30-56). Fatty alcohol is in the range of 1-20%, preferred 5-10% in cream (col. 10, line35-42) and the amount of fatty ester in lotion is about 0.10 to 10%, preferred 0.5-2% (col. 14, lines 50-55).

Poulsen (USPN 3,934,013) does not teach expressly the employment of second enhancer, or some of the particular percentages of corticosteroid or propylene glycol herein.

However, Bennett et al. teaches that combine two or more penetration enhancer, such as propylene glycol with azone and DMF is better than propylene glycol alone. See, particularly, the abstract.

Therefore, It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ two or more penetration enhancers as taught by Bennett in the composition of Poulsen.

One of ordinary skill in the art would have been motivated to employ two or more penetration enhancers as taught by Bennett in the composition of Poulsen because such combination are known to provide better efficacy of the active agent.

Further, the employment of corticosteroid and propylene glycol in the particular weight percentages claimed herein would have been within the purview of ordinary skilled artisan because ranges covering the instant weight percentages are taught to be useful in topical formulations by the prior art.

5. Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poulsen (US 3,934,013) as applied to claims 1-7 and 10, 13-19 above, and further in view of PDR entries of Lidex-Synalar.

Poulsen (USPN 3,934,013) does not teach the employment of the second penetration enhancer recited in the claims.

PDR entries of Lidex-Synalar teaches the employment of propylene glycol and diisopropyl adipate together in a topical fluocinonide composition. PDR also teaches different excipients and adjuvants that can be employed in a topical fluocinonide composition.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the two penetration enhancers and any known pharmaceutical necessity in the amounts herein in a corticosteroid topical composition, such as fluocinolone composition.

One of ordinary skill in the art would have been motivated to employ the two penetration enhancers and any known pharmaceutical necessity in the amounts herein in a corticosteroid composition, such as fluocinonide composition, because the two are known to be used together in such composition. Further, optimization of amounts of the penetration enhancers the optimization of a result effective parameter, e.g., amounts of the penetration enhancers, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215. Note penetration enhancers in topical pharmaceutical composition have been recognized as result affecting factor.

Response to the Arguments

6. The terminal disclaimer submitted November 16, 2007 is current under review, the ODP rejections over US patent 6,765,001 will be withdrawn once the terminal disclaimer is found proper.

7. Applicants' remarks and declaration under 37 CFR 1.132 submitted November 16, 2007 have been fully considered, but are unpersuasive.

8. The declaration under 37 CFR 1.132 filed November 16, 2007 is insufficient to overcome the rejection of claims 1, 2, 4-10 and 13-19 based upon Paulson et al as set forth in the last Office action because: .

9. It refer(s) only to the system described in the above referenced application and not to the individual claims of the application. Particularly, as shown in the specification, it only limited to the particular glucocorticoid with particular penetration enhancers. Thus, there is no showing

that the objective evidence of nonobviousness is commensurate in scope with the claims. See MPEP § 716.

10. In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Applicants remarks as to PE ratio (penetration enhancers/(penetration enhancer + solvent and emulsifiers) are not persuasive. One of ordinary skill in the art would have recognized that the concentration of penetration enhancer would be a result affecting parameters and optimization of such parameter would have been within the purview of an ordinary skilled artisan. Furthermore, more penetration enhancer, more penetration. Is that obvious?

Applicant further contend that the claims are not obvious over Paulson et al. as Paulson et al. do not teach fatty alcohol as penetration enhancer. The arguments are unpersuasive.

11. First, it is well understood that the claims are given the broadest interpretation during the examination. The claims are reasonably construed to encompass any compound that enhance penetration as penetration enhancers. Further, the intended function of a component in a composition would not carrier any patentable weight as it does not further limit the composition. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shengjun Wang
Primary Examiner
Art Unit 1617

/Shengjun Wang/

Primary Examiner, Art Unit 1617